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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,714	02/20/2004	Huddee Jacob Ho	MNOAP006	5606
23689	7590	01/23/2006	EXAMINER	
Jung-hua Kuo Attorney At Law PO Box 3275 Los Altos, CA 94024			TOY, ALEX B	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/783,714	Applicant(s) HO ET AL.	
	Examiner Alex B. Toy	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 2, 3, 5, 9, 10, 12-14, 19 and 28-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6-8, 11, 15-18, 20-27 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/24/04; 7/15/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Species VI shown in Figs. 3C-3D in the reply filed on December 19, 2005 is acknowledged. In the remarks, applicant recited that: "Claims 1, 4, 6-11, 15-18, 2-7, and 32-34 are readable on Species VI." For the purposes of examination, it is assumed that applicant intended to recite claims 20-27 and not claims 2-7. Claims 2-3, 5, 12-14, 19, and 28-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. In addition, the examiner withdraws claim 9 as being drawn to Species II shown in Figs. 1C-1D and claim 10 as being drawn to Species IX shown in Figs. 4A-4B.

In summary, claims 2-3, 5, 9-10, 12-14, 19, and 28-31 are withdrawn from further consideration. Claims 1, 4, 6-8, 11, 15-18, 20-27, and 32-34 are examined.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the tissue collector and tissue marking mechanism specified in claims 21-22 and 33-34 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

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prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In paragraph 43 (pg. 13-14), applicant does not sufficiently describe the

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compound or mechanism used to mark tissue in such a way as to enable its use in the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6-8, 15-18, and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Burbank (U.S. Pat. No. 6,331,166).

Regarding claim 1, Burbank discloses a tissue cutting device, comprising:

a probe 18 having a length generally defining a probe axis 19, the probe defining at least one cutting loop exit 48 at an exit angle relative to the probe axis, the exit being at a distal region of the probe (Fig. 1);

a cutting loop 20 with shape memory having a preconfigured shape (col. 4, ln. 60-62), the cutting loop being selectively in one of a penetrating configuration configured for the cutting device to penetrate tissue and a cutting configuration configured for the cutting loop to cut tissue, the cutting loop being generally within a profile of the probe in the penetrating configuration, and when in the cutting configuration, the cutting loop extends through the cutting loop exit and generally returns to the preconfigured shape, the cutting loop being at a cutting angle relative to the probe axis generally defined by the exit angle (col. 4, ln. 55-60 and Fig. 1); and

a cutting loop securing mechanism 30 configured to selectively secure the cutting loop 20 in the penetrating configuration and to release the cutting loop into the cutting configuration, the cutting loop securing mechanism being one of slidably disposed relative to the probe (col. 7, ln. 6-10 and Fig. 1) and a groove defined in the probe proximal to the cutting loop exit.

Regarding claim 4, Burbank discloses the device of claim 1, wherein the cutting loop securing mechanism 30 is a cover slidably disposed over probe 18 and configured to secure the cutting loop between the loop cover and the probe for the penetrating configuration (col. 7, ln. 6-10 and Fig. 1).

Regarding claim 6, Burbank discloses the device of claim 1, wherein the probe includes at least one cutting loop channel terminating at the cutting loop exit (col. 5, ln. 53-62 and Fig. 1).

Regarding claim 7, Burbank discloses the device of claim 1, wherein the size of the cutting loop is adjustable by retracting or extending the cutting loop into and out of the probe when the cutting loop is in a cutting configuration (col. 6, ln. 9-57 and Figs. 8-10).

Regarding claim 8, Burbank discloses the device of claim 1, wherein the probe defines two cutting loop exits (at the proximal and distal ends of recess 48) through which the cutting loop extends (Fig. 1).

Regarding claim 15, Burbank discloses the device of claim 1, further comprising a loop cover 30 disposed slidably over probe 18, the loop cover configured to secure the cutting loop between the loop cover and the probe for the penetrating configuration

and to release the cutting loop into its preconfigured shape for the penetrating configuration (col. 7, ln. 6-10 and Fig. 1).

Regarding claim 16, Burbank discloses the device of claim 1, wherein the cutting loop 20 is coupled to an energy source configured to supply energy to the cutting loop to facilitate cutting of tissue by the cutting loop (col. 4, ln. 64-66).

Regarding claim 17, Burbank discloses the device of claims 1 and 16, wherein the energy source is selected from at least one of a radio frequency, laser, water jet, air abrasion, ultrasonic, oscillation along a predetermined distance, direction and/or frequency, oscillation along a variable distance, direction and/or frequency (col. 4, ln. 64-66).

Regarding claim 18, Burbank discloses the device of claims 1 and 16, wherein the cutting loop 20 is partially insulated 30 to selectively expose the tissue to the energy (Fig. 1).

Regarding claim 20, Burbank discloses the device of claim 1, further comprising a probe locating mechanism housed in the probe, the probe locating mechanism facilitates in determining the location of at least one of the probe and the cutting loop within the tissue from external to the tissue, the probe locating mechanism being one of a light, a radiologic marker, and an ultrasound marker (col. 5, ln. 24-31). Since Burbank discloses using ultrasound as a probe locating mechanism, the probe of Burbank must inherently comprise a probe locating mechanism in the probe.

Regarding claim 21, Burbank discloses the device of claim 1, further comprising a tissue collector to collect tissue cut by the cutting loop (col. 8, ln. 39-46).

Claims 23-24 and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Dulebohn (U.S. Pat. No. 5,201,741).

Regarding claim 23, Dulebohn discloses a method for cutting targeted tissue, comprising:

positioning a tissue cutting device 10 adjacent to the targeted tissue, such that a distal end 52 of a probe 50 of the tissue cutting device is distal to the targeted tissue, the probe having a length generally defining a probe axis and the probe defining at least one cutting loop exit 54 at an exit angle relative to the probe axis, the exit being at a distal region of the probe;

releasing 58 a cutting loop 16 of the tissue cutting device from being generally parallel to the probe axis in a penetrating configuration to a cutting configuration, the cutting loop having shape memory (col. 4, ln. 42-48) with a preconfigured shape such that upon releasing the cutting loop, the cutting loop generally returns to the preconfigured shape and generally extends at a cutting angle relative to the probe axis defined by the exit angle (col. 7, ln. 57-62); and

retracting the tissue cutting device so that the cutting loop in the cutting configuration cuts the targeted tissue (col. 3, ln. 1-9).

See Figs. 8-9.

Regarding claim 24, Dulebohn discloses the tissue cutting method of claim 23, further comprising returning the cutting loop to the penetrating configuration when the cutting loop is proximal to the targeted tissue (col. 3, ln. 6-11).

Regarding claim 32, Dulebohn discloses the tissue cutting method of claim 23, further comprising adjusting the size of the cutting loop to generally encircle the targeted tissue (col. 3, ln. 1-6).

Regarding claim 33, Dulebohn discloses the tissue cutting method of claim 23, wherein the retracting is such that a tissue collector follows the path of the cutting loop to collect the cut tissue (col. 3, ln. 6-11 and col. 7, ln. 45-55). In the device of Dulebohn, the cutting loop 16 also serves as the tissue collector.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 11 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Burbank ('166).

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Regarding claim 11, Burbank discloses the device of claim 1. Since Burbank discloses that element 20 is a cutter (col. 4, ln. 64-65), it would be obvious, if not inherent, to have at least one edge of the cutting loop to be at least one of sharpened and serrated in order to facilitate cutting.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank ('166) in view of Nakao (U.S. Pat. No. 5,336,227).

Regarding claim 22, Burbank discloses the device of claim 1. The claim differs from Burbank in calling for a tissue marking mechanism to mark the tissue cut by the cutting loop. Nakao, however, teaches a tissue marking mechanism to mark the tissue cut by the cutting loop and the internal site of cutting in order to match a severed tissue sample with the respective site within the patient (col. 3, ln. 17-44). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included a tissue marking mechanism as claimed in the device of Burbank in view of the teaching of Nakao in order to match a severed tissue sample with the respective site within the patient.

Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dulebohn ('741) in view of Burbank ('166).

Regarding claim 25, Dulebohn discloses the tissue cutting method of claim 23. The claim differs from Dulebohn in calling for applying an energy to the cutting loop to facilitate cutting of tissue during the retracting. Burbank, however, teaches a surgical

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snare and applying an energy to the cutting loop to facilitate cutting of tissue (col. 4, ln. 64-66). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied an energy to the cutting loop of Dulebohn in view of the teaching of Burbank in order to facilitate cutting of tissue during the retracting.

Regarding claim 26, Dulebohn discloses the tissue cutting method of claims 23 and 25 in view of Burbank. In addition, Burbank teaches that the energy comprises radio frequency energy, a type of energy that is well-known in the art.

Regarding claim 27, Dulebohn discloses the tissue cutting method of claims 23 and 25 in view of Burbank. 27. Given that the method of Dulebohn selectively exposes the cutting loop (Fig. 8) and that Burbank teaches that his cutting loop is partially insulated 30 to selectively expose the tissue to the energy being applied (Figs. 8-10), it would be obvious to partially insulate the energized device of Dulebohn in view of Burbank in order to selectively expose the tissue to the energy being applied.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dulebohn ('741) in view of Nakao ('227).

Regarding claim 34, Dulebohn discloses the tissue cutting method of claim 23. The claim differs from Dulebohn in calling for marking the cut tissue using a tissue marking mechanism during the retracting. Nakao, however, teaches marking the cut tissue using a tissue marking mechanism during the retracting and marking the internal site of cutting in order to match a severed tissue sample with the respective site within

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the patient (col. 3, ln. 17-44). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included a tissue marking mechanism as claimed in the device of Dulebohn in view of the teaching of Nakao in order to match a severed tissue sample with the respective site within the patient.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 3739784 A	USPAT	Itoh; Mitsuto
US 5190542 A	USPAT	Nakao; Naomi L. et al.
US 5190555 A	USPAT	Wetter; Lowell A. et al.
US 5192286 A	USPAT	Phan; Cu N. et al.
US 5415656 A	USPAT	Tihon; Claude et al.
US 20030109874 A1	US-PGPUB	Dennis, William G.
US 20030163129 A1	US-PGPUB	Lee, Roberta et al.
US 6852111 B1	USPAT	Lieber; David

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT *AT*
1/18/06

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER